510(k) Summary for the Young Again

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1.General Information

Submitter:	Espansione Marketing Spa is located at: Blocco 27 – Via Orefici 152 Centergross 40050 Funo – Bologna S.p.A. Italy
Contact Person:	Guido Bonapace ISEMED srl Via A. Altobelli Bonetti 3/A 40026 Imola (BO) Italy Mob.phone: +39-335-5378686 Telephone: +39-0542 683803 Fax: +39-0542 698456 Email: regulatory@isemed.eu
Summary Preparation Date:	December 21, 2012

2.2. Names

Device Name:	Young Again
Classification Name:	Laser Surgical Instrument for use in General and PlasticSurgery and in Dermatology
Product Code:	OHS
Regulation number:	878.4810

2.3. Predicate Devices

The Young Again is substantially equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
Photo Therapeutics Inc.	Omnilux New-U	K072459
Espansione Marketing SPA	E-Light Line	K092734
Home Skinovations LTD	Silk'n FX	K110301

2.4. Device Description

The Young Again is a device which allows emission and treatment with LED light in the RED (634 nm) and IR (830nm) spectrum. The Young Again devices include a main unit installed on a trolley support, that controls and manages the LED emission through the two facial masks. The facial masks are designed in two versions depending upon the features of the LED installed in the mask: Red or IR The control panel is placed in the main unit with all the circuitry necessary to control the device and the user interacts with the Young Again device through the touch screen panel of the main unit and through a specific software application that allow the precise control of the treatment time.

2.5. Indications for Use

The Young Again is an over the counter device intended to emit energy in the red and IR region of the spectrum for use in dermatology for treatment of periorbital wrinkles.

2.6. Performance Data

In order to evaluate if the lay person could understand, select and use the device, Espansione Marketing has conducted a self-selection and usability test.
The Young Again software was tested and validated in accordance with the FDA "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices".
The Young Again energy densityand the standard dose was measured for the Young Again device with the two Red & IR masks, in a specific performance test. The results of this test allow to confirmthat the performance of the device with its masks are as expected. Furthermore these results were used to compare the technical parameters of the Young Again device to the predicate device
Young Again device has been developed and tested according to the following international standards: IEC 60601-1, IEC 60601-1-2, IEC 62304, ISO , ISO /FDIS 15223-1, and ISO 10993-1 recognized by FDA.

Based upon an analysisof the overall performance technical features in the substantial equivalence discussion for the device, Espansione Marketing believes that no significant differences exist between the previously approved Espansione Marketing devices (E-light line K092734) and the other predicate devices Photo Therapeutics Omnilux New-U (K072459) and Home SkinovationsSilk'n FX (K110301).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Espansione Marketing Spa
% Mr. Guido Bonapace
Isemed Srl
Via Altobelli Boneti 3A
Imola, Bologna 40026
ITALY

December 19, 2013

Re: K124064
Trade/Device Name: Young Again
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: December 5, 2013
Received: December 11, 2013

Dear Mr. Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124064

Device Name: Young Again

Indications For Use: The Young Again is an over the counter device intended to emit energy in the red and IR region of the spectrum for use in dermatology for treatment of periorbital wrinkles.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K124064